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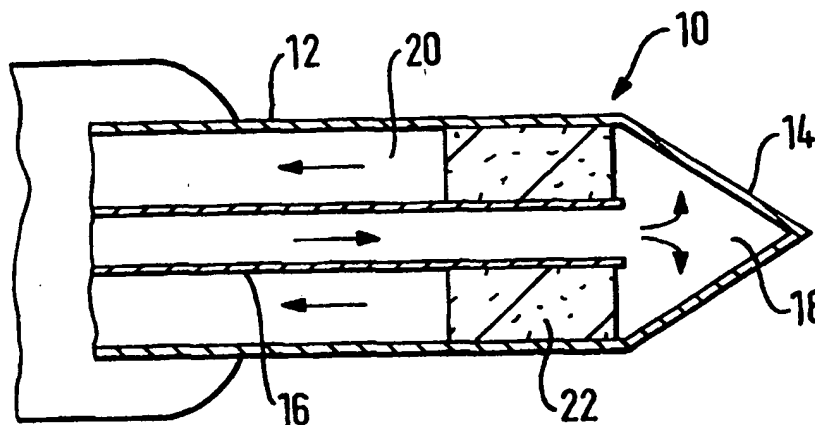
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/GB99/01353</p> <p>(22) International Filing Date: 30 April 1999 (30.04.99)</p> <p>(30) Priority Data: 9809343.8 30 April 1998 (30.04.98) GB</p> <p>(71) Applicant (for all designated States except US): SPEMBLY MEDICAL LIMITED [GB/GB]; Newbury Road, Andover, Hampshire SP10 4DR (GB).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): CUFF, Louise [GB/GB]; 65 Armstrong Rise, Charlton, Andover, Hampshire SP10 4EB (GB). CLARKE, Brian [GB/GB]; Cryomedical Instruments Ltd., Cryomed House, Grove Way, Mansfield Woodhouse, Nottinghamshire NG19 8BW (GB).</p> <p>(74) Agent: HOLMES, Miles, Keeton; D Young & Co., 21 New Fetter Lane, London EC4A 1DA (GB).</p>		<p>(81) Designated States: JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published With international search report.</p>

(54) Title: IMPROVEMENTS RELATING TO CRYOSURGICAL APPARATUS



(57) Abstract

In a cryosurgical probe (10) cooled by vaporisation of liquid cryogen, a member (22) of sintered metal in the cryogen flow path acts as a phase dependent resistance, the member (22) providing a higher resistance to the flow therethrough of liquid cryogen than to the flow of cryogen gas. In a preferred form, the member (22) is arranged in the exhaust path (20) immediately downstream of the boiling tip (14). The member surrounds a delivery conduit (16), and is in thermal contact with the delivery conduit (16) and the outer probe casing (12). The member slows the exhaust of any liquid cryogen which has not yet boiled, and allows additional boiling within the member (22) to provide additional cooling of the probe tip. In another preferred form, the member (22) is arranged within the delivery conduit to regulate the flow of liquid and gaseous cryogen to the boiling region.

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IMPROVEMENTS RELATING TO CRYOSURGICAL APPARATUS

This invention relates to cryosurgical apparatus, in particular to cryosurgical apparatus which uses liquid cryogen, for example, liquid nitrogen, to effect cooling.

5 Many designs of liquid cryogen instruments are known. A problem which has been encountered, particularly in instruments or apparatus employing narrow bore delivery conduits, is the formation of cryogen gas within the delivery conduit. The problem is most apparent during the early stages of a cooling cycle, when the conduit walls are relatively warm, and cryogen liquid contacting the conduit wall boils in the
10 conduit producing cryogen gas. Even once the system becomes cool, the conduit walls are not quite at cryogenic temperatures, and still result in some of the cryogen vaporising within the conduit, thereby creating laminar flow. Normally, the cryogen arriving at the cooling tip of a probe will be a mixture of useful cryogen liquid, and "expended" cryogen gas. In order to ensure that sufficient liquid cryogen reaches the
15 probe tip, the cryogen tends to be supplied at a relatively high rate. This can result in inefficient boiling, and places a heavy demand on the cryogen supply system. This is one of the factors which can limit the maximum duration of a cryosurgical operation.

WO-A-93/04647 describes a probe in which vent apertures are provided within the wall of the delivery conduit to allow gas to vent directly into a concentric exhaust
20 path, and be carried away with the exhaust. This is said to increase the rate of flow of liquid cryogen through the probe tip, and thereby increase cooling efficiency. However, with such a design, the aperture size is critical to the performance of the probe. If the apertures are too large, a significant amount of liquid cryogen will leak into the exhaust path, resulting in cryogen wastage. If the apertures are too small, they
25 will tend to block and will fail to vent enough gas from the delivery conduit.

An elaborate probe is described in WO-A-95/30379 and WO-A-95/30380, in which a separate bypass path is provided with a controllable valve. During the initial stage of the cooling cycle, the valve is open to allow gas to vent directly, and thereby increase the flow through the delivery conduit. Once the system has cooled and liquid
30 cryogen reaches the probe tip, the valve can be closed to stop the flow through the

bypass path. However, with such an arrangement, any gas which develops in the delivery conduit then has to pass through the probe tip with the main stream of liquid cryogen.

In the above WO-A-95/30379 and WO-A-95/30380, a metal heatsink conduit is
5 arranged at the probe tip, in thermal contact with the tip casing. The incoming liquid conduit flows through the conduit, and the exhaust gas flows between the conduit and the casing. This is said to result in improved boiling characteristics.

The present invention has been devised bearing in mind the liquid/gas problems discussed above.

10 Broadly speaking, one aspect of the present invention is to provide in a cryogen fluid path a means through or around which, in use, cryogen fluid in a liquid phase and a gaseous phase can flow, the means presenting a greater resistance in the path to the flow of liquid than to the flow of gas.

Such a means is referred to herein as a phase dependent resistance (PDR).
15 Preferably, the PDR is arranged within the boiling on or within a cryogen path, which communicates with the instrument's boiling region. Preferably, the PDR occupies the full width of the path in which it is situated, such that cryogenic fluid in the path is substantially unable to bypass the PDR.

The present invention has arisen out of an appreciation that good thermal
20 efficiency can be obtained with a low flow rate for liquid cryogen in the apparatus, and a high flow rate for vaporised cryogen.

The low liquid flow rate means that the liquid cryogen flows through the boiling region relatively slowly, and there is sufficient time for almost all of the liquid to vaporise within the instrument's boiling region. If the liquid flow rate is too high, a
25 significant proportion of liquid will pass through the boiling region into the exhaust path without having time to boil, and will be wasted. This is believed to be a factor not hitherto appreciated, which limits the performance of many conventional designs. A low liquid flow rate also places less demand on the liquid cryogen supply, allowing longer operations to be carried out. This is especially important for systems with a
30 limited cryogen supply.

The high gas flow rate can prevent back pressure from developing within the instrument. When, for example, liquid nitrogen boils, its volume expands by a factor of about 700. It is important that the gas developed be able to escape relatively unhindered, so that boiling can take place continuously. The high gas flow rate can
5 also enable gas developed in the cryogen delivery tube to pass through the instrument relatively unhindered.

Preferably, the PDR is in thermal contact with the outer case of the boiling region and/or with the conduit for delivering conduit to the boiling region. Preferably, the PDR is in intimate thermal contact with the case and/or inner conduit.

10 Preferably, the PDR is of metal or of other thermally conductive material.

Preferably, the PDR comprises a porous member, more preferably a member of sintered material.

Preferably, the PDR is generally rigid.

One or more PDR's may be used in the cryogen flow path, as desired, within a
15 cryosurgical instrument and/or within supply apparatus for supplying liquid cryogen to a cryosurgical instrument.

For example, a PDR may be arranged at, or adjacent to the boiling/cooling region.

A PDR may be arranged, for example, in the exhaust path immediately
20 downstream from the boiling region. In that case, the PDR can provide additional surface area against which the liquid cryogen can boil.

Alternatively, or additionally, a PDR may be arranged within a supply conduit to regulate the relative flow rates of liquid cryogen and vaporised cryogen to the boiling region.

25 In a closely related aspect, the invention provides liquid cryogen apparatus comprising sintered material arranged within a cryogen flow path. Preferably, the sintered material is disposed in the cryogen flow path through a boiling region of a cryosurgical instrument, such that cryogen passing through the boiling region also passes through the sintered material. The sintered material may be arranged within the

cryosurgical instrument and/or within a supply apparatus for supplying liquid cryogen to a cryosurgical instrument.

Preferably, the sintered material is sintered metal, for example, sintered stainless steel, or sintered bronze.

5 Preferably, the sinter size gives the material a porosity in a range of from about 10 micron maximum particle retention (MPR), to about 40 micron MPR.

It is believed that the sintered material acts as a PDR to allow the flow of gas therethrough at a higher flow rate than the rate therethrough of liquid. The relative flow rates can be controlled by the porosity of the sintered material, and the length of
10 the flow path through the sintered material.

Preferably, the sintered material is in thermal contact with an outer case of a boiling region of a cryosurgical instrument and/or with a delivery conduit for the liquid cryogen.

In a further aspect, the invention provides a method of controlling the flow of a
15 mixture of liquid and gaseous cryogen within cryosurgical apparatus, the method comprising passing the cryogen mixture into a member of sintered material, to provide a greater resistance to the passage of liquid cryogen than to the passage of gaseous cryogen.

Preferably, the method further includes the step of vaporising at least a portion
20 of the liquid cryogen within the sintered member.

Embodiments of the invention are now described, by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a schematic section through the cooling tip of cryosurgical probe;

Fig. 2 is a schematic section showing a modified design similar to that shown in
25 Fig. 1;

Fig. 3 is a schematic section showing a further embodiment of a cryosurgical probe; and

Fig. 4 is a schematic section showing a fourth embodiment of probe.

Referring to Fig. 1, a cryosurgical probe 10 comprises an outer conduit case 12
30 having a tip 14 and containing an inner delivery conduit 16 arranged concentrically

therewithin. The region 18 defined within the tip 14 is a cryogen boiling region within which liquid cryogen supplied through the inner conduit 16 vaporises to generate cooling. The vaporised gas exhausts through an annular exhaust path 20 defined between the inner conduit 16 and the outer conduit 12. A thermal insulation region 22
5 extends along the probe, terminating a short distance from the tip region. The outer and inner conduits 12 and 16 are typically made of metal, such as stainless steel or silver.

The probe construction described thus far is generally conventional. The probe may include other conventional features and details not described or illustrated herein.

10 In this embodiment, an annular porous element 24 is arranged outside the inner conduit 16 immediately adjacent to the boiling region 18, so that it is immediately downstream of the boiling region 18. Cryogen leaving the boiling region 18 passes through the porous element as it enters the exhaust path 20. The porous element 24 is made of sintered metal, for example, sintered stainless steel or sintered bronze.

15 The porous element 24 is believed to provide the following advantageous effects:

(a) The porous element acts as a PDR which provides a higher resistance to the flow of liquid cryogen therethrough than to the flow of vaporised cryogen. Thus, any cryogen remaining unboiled after exiting the boiling region 18 passes only relatively
20 slowly through the porous member 24, whereas vaporised gas passes through the porous member 24 relatively unhindered. Therefore, although the exhausting of gas is unhindered, the rate of flow of liquid tending to exhaust is very much reduced, which provides more time for the liquid to boil in the boiling region 18.

(b) The porous element 24 provides extra opportunity for cryogen liquid passing
25 therethrough to boil, and thus enhance the cooling efficiency of the probe, rather than being wasted in the probe exhaust. The member 24 provides a relatively large surface area against which the cryogen can boil, and there is additional potential for the pressurised volatile cryogen to boil, in order to pass through the porous member more easily.

(c) The porous element 24 is in good thermal contact with the outer conduit case 12, such that the additional cooling generated by boiling of excess cryogen passing through the porous element 24 (which is immediately downstream of the boiling region 18) is communicated to the exterior of the probe, in order to improve probe efficiency.

5 (d) The porous element is additionally in good thermal contact with the inner conduit 16, such that the additional cooling generated by boiling of excess cryogen passing therethrough is communicated to the inner conduit 16, to reduce the generation of vapour within the delivery conduit, and to improve the flow characteristics of the liquid cryogen for optimum boiling.

10 It will be appreciated that the use of the element 24 of porous material can combine the heatsink benefits described in the above mentioned WO-A-95/30379 and WO-A-95/30380, with PDR characteristics to ensure that gas flow is not impeded, while the flow rate of liquid cryogen through the heatsink is reduced for increased boiling efficiency.

15 In this embodiment, the porous element 24 is dimensioned to be a tight fit against the inner conduit 16 and the outer conduit 12. However, if desired, additional fixing may be used, for example, a screw threaded coupling between the inner conduit 16 and the porous element 24 and/or between the outer conduit 12 and the porous element 24. It will also be appreciated that, while desirable, good thermal contact with
20 the inner conduit 16 and the outer conduit 12 is not essential in all embodiments. The PDR characteristics are not dependent on such thermal contact.

Fig. 2 illustrates a modified embodiment in which a plurality of discrete porous elements 24 are arranged spaced apart in series in the exhaust path downstream of the boiling region 18. In this embodiment, each porous element provides additional PDR
25 characteristics as described above. The porous elements could also be arranged contiguously, or a single elongate porous element used instead, if desired.

Fig. 3 illustrates an alternative embodiment in which one or more porous elements 26 are arranged within the inner delivery conduit 16; three elements 26 are illustrated. The elements 26 are similar to the elements 24 discussed above, and

comprise sintered metal. However, instead of being annular, the elements 26 are shaped as plugs fitted within the inner conduit 16.

In this embodiment, the porous elements 26 function as PDR's to regulate the flow of liquid cryogen delivered to the boiling region 18 of the probe. As explained previously, the cryogen in the delivery conduit will be a mixture of liquid cryogen, and vaporised cryogen. Cryogen gas developing within the conduit 16 passes through the porous elements 26 relatively unhindered, whereas liquid cryogen passes through each porous element 26 relatively slowly. The result is that, even if cryogen is supplied at relatively high pressure, the liquid flow rate is controlled to be relatively small, such that the liquid cryogen passes into the boiling region 18 relatively slowly, and has adequate time to boil completely.

It will be appreciated that, in this embodiment, the porous elements 26 in the inner (delivery) conduit 16 serve merely as PDR's, not as additional boiling regions for the liquid cryogen.

In use, pools or reservoirs 28 of liquid cryogen will tend to collect between the porous elements 26, and the rate of liquid flow through each porous element 26 will depend on the head of liquid upstream of the element. Should a pool fill, or become nearly full, the pressure of cryogen gas will force a short burst of liquid cryogen through the element 26 to clear a gas path again. Thus the system is self-regulating, and maintains open a gas flow path so that gas flows through relatively unhindered.

In Fig. 3, the porous elements 26 are illustrated in the probe itself. However, it will be appreciated that one or more porous elements 26 may be provided in liquid cryogen delivery apparatus, if desired, to function as a PDR.

Although rigid sintered metal elements have been described above as the porous elements 24 and 26, it will be appreciated that any suitable element may be used which can provide a higher resistance to liquid flow than to gas flow, while permitting, in use, sufficient flow therethrough or therepast.

The above embodiments employ concentric passages defining an inlet channel and an exhaust channel communicating with the cooling region. This is a preferred, but not essential construction of probe.

In the illustrated embodiments, the central passage provides the inlet channel and the outer passage provides the exhaust channel. However, in other embodiments, the roles of the passages may be swapped, such that incoming cryogen is delivered through the outer passage, and exhaust cryogen leaves through the central passage. In
5 such an alternative embodiment, a PDR, or a sintered member, may be used in a manner similar to any of the foregoing arrangements. In particular, the member may be arranged within the cooling region, or upstream of the cooling region, or downstream of the cooling region.

For example, Fig. 4 illustrates an embodiment with an outer delivery conduit
10 passage 30 defined between the case 12 and the inner tube 16, and an inner exhaust passage 32 defined by the inner tube 16. The boiling region 18 is elongate, and is defined at the tip. A plurality (three in this embodiment) of annular sintered metal PDR members 24 are arranged in the boiling region 18. The members are shown
equally spaced apart, but the spacing may be varied as desired. In this embodiment,
15 the members 24 function as PDR's and also as heatsink surfaces to promote boiling of the liquid cryogen in the boiling region 18.

The members 24 are dimensioned to be an interference fit against the inner surface of the case 12, and a push fit on the inner tube 16.

A conventional vacuum jacket assembly 34 insulates the probe shaft to promote
20 boiling in the boiling region 18, and to prevent unwanted ice-ball growth along the shaft in use of the probe.

In the above embodiments, the cooling region of the apparatus is illustrated at the tip of the probe. It will be appreciated that this is purely illustrative, and that the cooling region may be located anywhere as desired, depending on the design of the
25 probe or other apparatus.

It will be appreciated that the invention, particularly as described above, can enable the efficiency of a liquid cryogen instrument to be increased, and can reduce wasteful consumption of the liquid cryogen. With the invention, it may also be possible to avoid the need for a gas bypass path as used in the above mentioned WO-A-

95/30379 and WO-A-95/30380 depending on the design of the probe. However, such a bypass path may be used in combination with the present invention.

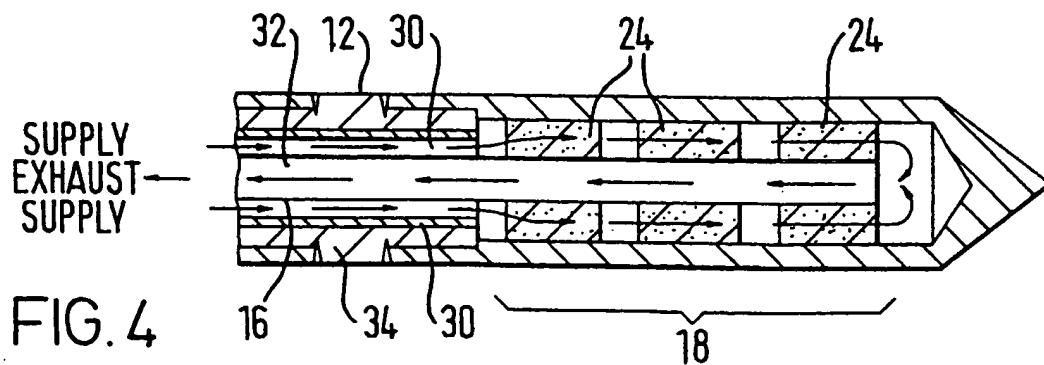
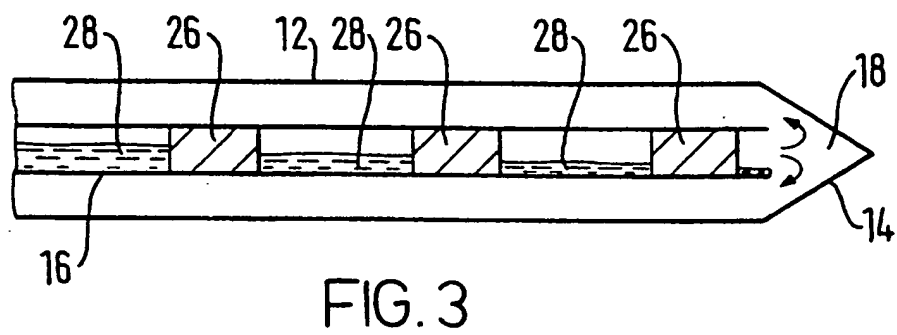
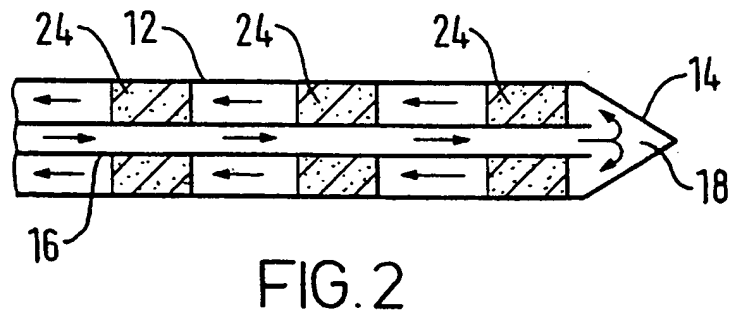
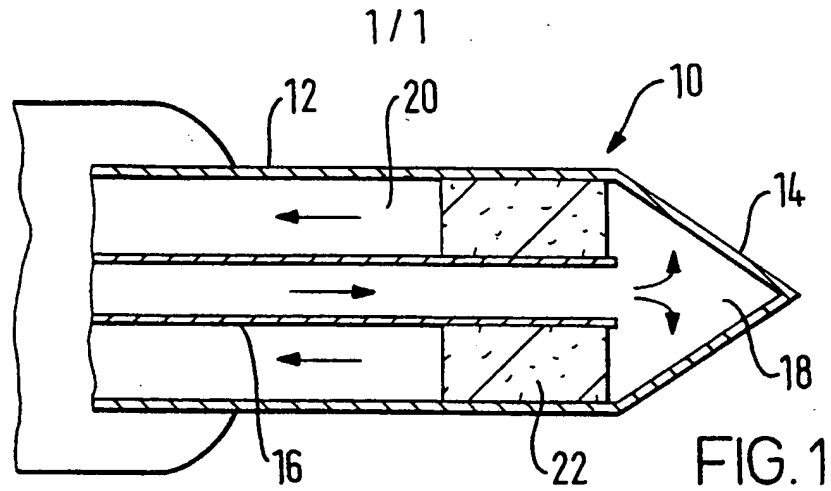
While features believed to be of particular significance have been emphasised in the forgoing description and the appended claims, the applicant claims protection for
5 any novel idea, feature or combination of features disclosed herein and/or illustrated in the accompanying drawings, irrespective of whether emphasis has been placed thereon.

CLAIMS

1. Apparatus for use in cryosurgery comprising a cryogen fluid flow path which is in line with, or in use is connected to be in line with, a boiling region for liquid
5 cryogen, and a phase dependent resistance in the flow path, the phase dependent resistance presenting a greater resistance to the flow of liquid cryogen in the flow path than to the flow of gaseous cryogen.
2. Cryosurgical apparatus operable to be cooled by vaporisation of liquid cryogen
10 supplied thereto, comprising a boiling region for liquid cryogen, a flow path for cryogen fluid through the boiling region, and a phase dependent resistance within the flow path, the phase dependent resistance presenting a greater resistance to the flow of liquid cryogen in the flow path than to the flow of gaseous cryogen.
- 15 3. Apparatus according to claim 2, wherein the phase dependent resistance is located at, or adjacent to, the boiling region.
4. Apparatus according to claim 2 or 3, wherein the phase dependent resistance is located in, or at the entry to, a cryogen exhaust path for carrying exhaust cryogen from
20 the boiling region.
5. Apparatus according to claim 3 or 4, wherein the apparatus comprises an inner conduit defining a first fluid path communicating with the boiling region, a second path being immediately outside the inner conduit, wherein the phase dependent resistance
25 comprises an annular member mounted around the inner conduit.
6. Apparatus according to claim 5, wherein the phase dependent resistance is in thermal contact or thermal communication with the delivery conduit.

7. Apparatus according to claim 2, 3, 4, 5 or 6, wherein the phase dependent resistance is positioned adjacent to the cryogen boiling region.
8. Apparatus according to claim 2, 3, 4, 5, 6 or 7, further comprising a boiling
5 region casing of thermally conductive material, the phase dependent resistance being in thermal communication with the casing.
9. Apparatus according to claim 8, wherein the phase dependent resistance is in thermal contact with the casing.
- 10
10. Apparatus according to claim 1 or 2, wherein the phase dependent resistance is positioned within a delivery conduit for supplying cryogen to the, or to a said, cryogen boiling region.
- 15
11. Apparatus according to any preceding claim, wherein the phase dependent resistance comprises thermally conductive material.
12. Apparatus according to claim 11, wherein the phase dependent resistance is of metal.
- 20
13. Apparatus according to any preceding claim, wherein the phase dependent resistance comprises a porous member.
14. Apparatus according to claim 13, wherein the phase dependent resistance is of
25 sintered material.
15. Apparatus according to any preceding claim, comprising a plurality of phase dependent resistances.

16. Apparatus for use in cryosurgery, comprising a porous member of sintered material arranged within a cryogen flow path.
17. Apparatus according to claim 16, wherein the sintered material is metal.
- 5 18. Apparatus according to claim 16 or 17, wherein the sintered material is in the flow path through a cryogen boiling region of the apparatus.
19. Apparatus according to claim 16, 17 or 18, wherein the sintered material is
10 located at, or adjacent to, a cryogen boiling region of the apparatus.
20. Apparatus according to claim 16, 17, 18 or 19, wherein the member of sintered material is in thermal communication with an outer case of the boiling region.
- 15 21. Apparatus according to any preceding claim, wherein, in use, substantially all of the fluid in the fluid path in which the phase dependent resistance and/or sintered material is situated, flows in intimate contact with the phase dependent resistance or sintered material.
- 20 22. A method of controlling the flow of a mixture of liquid and gaseous cryogen within cryosurgical apparatus, the method comprising passing the cryogen mixture into a member of sintered material, to provide a greater resistance to the passage of liquid cryogen than to the passage of gaseous cryogen.
- 25 23. A method according to claim 22, further comprising the step of vaporising at least a portion of the liquid cryogen within the member of sintered material.
24. A method according to claim 22 or 23, wherein the sintered material is sintered metal.



INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 99/01353

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B F25B F25D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 4 202 336 A (VAN GERVEN HANS) 13 May 1980 (1980-05-13)	1-9, 11-14
X	column 2, line 56 - line 62	16-24
A	column 3, line 10 - line 12; figure 1	15
X	US 4 345 598 A (JELINEK JAN ET AL) 24 August 1982 (1982-08-24)	1-4,6-8, 10-14
X	column 2, line 63 - column 3, line 2; figure 1	16-24
X	US 5 452 582 A (LONGSWORTH RALPH C) 26 September 1995 (1995-09-26)	16-20
A	column 3, line 32 - line 39; figure 1	1-9,11, 13,14, 21,24
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	17 April 1997 (1997-04-17) page 11, line 14 - line 28; figure 3 -----	1-4, 6, 8-14, 21-24

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